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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/053,758   | 01/18/2002  | Thomas R. Cech       | 015389-002980US     | 6144             |
| 34151  | 7590        | 08/10/2005           | EXAMINER            |                  |
| TOWNSEND AND TOWNSEND AND CREW LLP<br>8TH FLOOR<br>TWO EMBARCADERO CENTER<br>SAN FRANCISCO, CA 94111 |             |                      | UNGAR, SUSAN NMN    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1642                |                  |

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/053,758             | CECH ET AL.         |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Susan Ungar            | 1642                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 25 May 2005.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-16, 20 and 23-26 is/are pending in the application.  
4a) Of the above claim(s) 9-16 and 20, 24, 26 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-8, 23 and 25 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All   b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_.  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

1. The Amendment filed May 25, 2005 in response to the Office Action of January 25, 2005 is acknowledged and has been entered. Previously pending claims 17-22 have been canceled, claims 1, 9 and 13 have been amended and claims 23-26 have been added. Claims 24 and 26 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions Claims 1-8, 23 and 25 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's request for priority for claims 25 based on the recitation of the structure and use of SEQ ID NO:67 in USSN 08/844,419 filed April 18, 1997 and USSN 08/846,017 filed April 25, 1997 is acknowledged. However, since the earlier filed Applications are not available to Examiner at this time, the priority claim cannot be evaluated. It is noted that Applicant has not pointed to page and line number of the cited Applications for support of the priority claim, Applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.
4. The following rejections are being maintained:

***Double Patenting***

5. Claims 1-8 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting for the reasons previously set forth.

Applicant argues that claims 50, 71, 73 of USSN 09/721,477 are not under examination. The argument has been considered but has not been found persuasive because the claims have not been canceled. Further, it is noted that claims 1 and 2 still conflict with claim 50 of USSN 09/721,477 because claim 50 has not been

canceled nor has Applicant demonstrated a clear line of demarcation between the applications.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

6. Claim 23 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an antibody that binds a polypeptide consisting of SEQ ID NO:225, but does not bind a polypeptide consisting of SEQ ID NO:67 has no clear support in the specification and the claims as originally filed. In the response filed May 25, 2005, Applicant points to support for the newly added claim limitations in SEQ ID NO:225, the protein sequence of full length hTRT and in SEQ ID NO:67, which is a portion of the hTRT protein, SEQ ID NO:225 shown in Figure 27. The suggested support has been considered but has not been found persuasive because the newly claimed limitation is not discussed, suggested or contemplated in the cited support. Applicant argues that when both a genus and a species or a subgenus are disclosed in a specification, case law permits applicant to claim the genus with a negative limitation to the species or subgenus and specifically cites *In re Johnson* wherein the court found that if alternative elements are positively recited in the specification, then they may be explicitly excluded from the claims. Applicant cites *Ex Parti Grasselli* wherein the court found that the specification having described the whole, necessarily described the part remaining. The arguments have been considered but have not been found persuasive because the newly added claims are not drawn to alternative elements and the fact patterns in the instant specification and in *In re Johnson* are not the same. A review of *In re Johnson* reveals that the claims are drawn to linear thermoplastic polyarylene

polyethers comprising alternative elements. The instant application is drawn to SEQ ID NO:225 and fragments thereof which is not commensurate in scope with thermoplastic polyarylene polyethers comprising alternative elements and therefore the findings of the court in *In re Johnson* are not relevant to the instant claims. Further, although the court found in *Ex parti Grasselli* that the specification, having described the whole, necessarily described the part remaining. There is nothing in the specification that supports the limitation of an antibody that binds to SEQ ID NO:225, but not to SEQ ID NO:67. It is noted that the MPEP at 2173.05(i) specifically states that “any negative limitation or exclusionary proviso must have basis in the original disclosure.”..... The mere absence of a positive recitation is not basis for an exclusion. It is clear that there is an absence of a positive recitation in this case and that the fragment of SEQ ID NO:225 is not an alternative element. The subject matter claimed in claim 23 broadens the scope of the invention as originally disclosed in the specification.

7. Claims 25 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an antibody that specifically binds to a polypeptide consisting of SEQ ID NO:67 has no clear support in the specification and the claims as originally filed. In the response filed May 25, 2005, Applicant points to support for the newly added claim limitation in SEQ ID NO:225, the protein sequence of full length hTRT and in SEQ ID NO:67, which is a portion of the hTRT protein, SEQ ID NO:225 shown in Figure 27. The suggested support has been considered but has not been found persuasive because the newly claimed limitation is not drawn to negative limitations and although a review of the specification revealed support for an antibody that binds specifically to a polypeptide comprising SEQ ID NO:67, a

review of the specification as originally filed did not reveal support for an antibody that specifically binds to a polypeptide consisting of SEQ ID NO:67. The subject matter claimed in claims 25 broadens the scope of the invention as originally disclosed in the specification. Applicant is invited to point to page and line number of the originally filed application, or those to which priority is claimed, which supports the newly added limitation.

8. All other objections and rejections set forth in the previous Office Action are hereby withdrawn.

9. No claims allowed.

10. Applicant's request for rejoinder of claims 9-16 and 24 and 26 is acknowledged. The claims, however, will not be rejoined because the claims currently under consideration have not been found to be allowable. Further, it is noted that even were the claims currently under consideration to be found allowable, claims 9-16, 24 and 26 are not commensurate in scope with the claims currently under prosecution since the claims under consideration are drawn to antibody that binds to hTRT, SEQ ID NO:225 and the method claims are not limited to methods of detecting hTRT, SEQ ID NO:225.

11. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

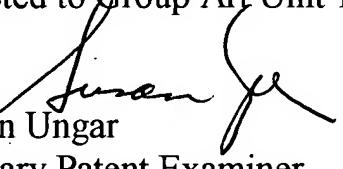
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan  
Primary Patent Examiner  
August 5, 2005